Bipolar Resectoscope
ACMI Corporation
136 Turnpike Road
Southborough, MA 02139

MAY 0 9 2002

Special 510(k) Notification
Summary of Safety and
Effectiveness
April 10, 2002

510(k) Summary of Safety and Effectiveness
ACMI Circon Corporation
ACMI Bipolar Resectoscope

General Information

Manufacturer:	ACMI Circon Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	9920160
Contact Person:	John A. DeLucia VP, Quality Assurance, Regulatory Affairs and Clinical Affairs
Date Prepared:	April 10, 2002

Device Description

Classification Name:	Endoscope and accessories (21CFR 876.1500)
Trade Name:	ACMI USA Elite Series Bipolar Resectoscope
Generic/Common Name:	Endoscope and accessories

Predicate Devices

ACMI USA Elite Resectoscope with Monopolar Working Element	Preamendment & K951972

Intended Uses

Intended for use in patients requiring endoscopic surgery for general urological tissue resection, ablation, and excision and hemostasis of blood vessels. These procedures include Bladder Tumor Diagnosis and Resection, Transurethral Prostatic and Bladder Biopsy, Transurethral Prostatic Resection, and Treatment of Vesical Neck Constriction.

Product Description

The USA Elite Bipolar Resectoscope consists of a Telescope, Sheath, Bipolar Working Element, and Obturator. The USA Elite Bipolar Resectoscope is

designed to work with currently marketed Electrosurgery Systems consisting of a electrosurgical generator called the Controller, a disposable Bipolar Loop, and a reusable or disposable Loop Cable or Cord.

This Special 510(k) proposes a modification in the performance specifications, dimensional specifications, materials, and labeling for The USA Elite Series Bipolar Resectoscope. The indications for use, principles of operation, the packaging materials, and the sterilization parameters of the USA Elite Bipolar Resectoscope remain the same as in the predicate device.

Summary of Safety and Effectiveness

The proposed modifications for the USA Elite Series Bipolar Resectoscope, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in performance specifications, dimensional specifications, materials, and labeling specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 09 2002

Mr. John A. DeLucia
Vice President, Quality Assurance,
Regulatory Affairs, Clinical Affairs
ACMI Corporation
Global Headquarters
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K021166
Trade/Device Name: ACMI-Circon Bipolar Resectoscopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDC and FBO
Dated: April 10, 2002
Received: April 11, 2002

Dear Mr. DeLucia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: ACMI Bipolar Resectoscope

510(k) Number:

Indications for use:

Intended for use in patients requiring endoscopic surgery for general urological tissue resection, ablation, and excision and hemostasis of blood vessels. These procedures include Bladder Tumor Diagnosis and Resection, Transurethral Prostatic and Bladder Biopsy, Transurethral Prostatic Resection, and Treatment of Vesical Neck Constriction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021166